

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC,)
REPAIR SYSTEM PRODUCTS)
LIABILITY LITIGATION) Master File No. 2:12-MD-02327
) MDL 2327
)
)
)
THIS DOCUMENT RELATES TO:) JOSEPH R. GOODWIN
WAVE 1 CASES) U.S. DISTRICT JUDGE
)
)

DECLARATION OF BRIAN J. FLYNN, M.D.

I, Brian J. Flynn, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am a urologist with a practice in female pelvic medicine and reconstructive surgery. I am the Co-director of Female Pelvic Medicine and Reconstructive Surgery and an Associate Professor of Surgery/Urology at the University of Colorado Denver.
2. I attended medical school at Temple University School of Medicine in Philadelphia, Pennsylvania, graduating in 1995. I went on to do a General Surgery Internship/Residency between July 1995 and June 1997 with Geisinger Health System in Danville, Pennsylvania. I then completed a Urology Residency between July 1997 and June 2001 with Geisinger Health System in Danville, Pennsylvania. I then completed a fellowship in Female Pelvic Medicine and Reconstructive Urology between July 2001 and June 2002 at Duke University Medical Center in Durham, North Carolina.
3. I am licensed to practice medicine in the State of Colorado.
4. I have been a Diplomate of the American Board of Urology since March 2004.

5. I have been provided with a copy of Plaintiffs' Emergency Motion to Reconsider the Scope of Wave 1 Defense Medical Exams and have reviewed that motion as it pertains to the medical examinations of Plaintiffs Monica Freitas and Patricia Ruiz.

6. I examined Mrs. Freitas on February 24, 2016 at the Centennial Medical Center in Centennial, Colorado, located at 13111 East Briarwood Avenue, Suite 105.

7. At the beginning of the IME, I explained to Mrs. Freitas the expectations of the IME and that a Doctor-patient relationship would not be established, and there would be no expectation that I would treat her in the future.

8. Mrs. Freitas elected to travel to the IME alone. She decided to travel without any friends or family.

9. I informed her that the IME would be similar to the IME performed by Dr. Margolis, to give her some expectations.

10. The IME took one hour and the majority of the time—approximately 50 minutes—was spent taking her history. In the interview, she did mention to me that she was having cramps and pelvic pain.

11. Part of the IME is a physical exam, and it is a basic medical principle to do a complete exam and especially focus the exam on the area of concern. This area was the pelvis, vagina, and the prior surgical site. These are the same areas examined in the IME performed by Dr. Margolis.

12. Before the physical exam, I made arrangements for a medical assistant from the office at which I was performing the IME to be present as an assistant. The medical assistant was present the entire time I examined Mrs. Freitas.

13. I explained to Mrs. Freitas what I was about to do during each portion of the exam. I gave her the option of deferring on the exam, but did stress to her the importance. Mrs. Freitas elected to proceed with the exam.

14. Following her permission, I inserted the plastic speculum into her vagina. She experienced pain and pulled away and to the top of the table. She began to cry.

15. I immediately stopped the exam and gave her a Kleenex. Approximately 5 minutes later she had regained her composure. The medical assistant offered to further comfort her by holding her hand, and she declined. I did not make any comments about her occupation.

16. Once she stopped crying and made eye contact with us, I asked her if she was OK. I did give her the following two options:

- a. To stop the exam and report my findings which were limited to only a 20 second vaginal/speculum exam. I informed her that I would report in the IME that the exam was incomplete.
- b. Allow me to complete the exam.

17. She chose the second option and allowed me to complete the exam. I noted the physical exam findings in my IME report. This included blood seen from the cervical os and superficial mesh. These findings were not evident during the initial part of the exam. Mrs. Freitas was not tearful, nor did she appear in pain during the 2nd portion of the exam. I did use a smaller speculum, which allows more patient comfort but compromises the examiners view of the vaginal wall.

18. A routine part of a pelvic exam in my practice includes a speculum exam. Also, I routinely ask patients to push and strain (Valsalva) to see if it induces urinary incontinence or prolapse.

19. I elected to not to perform a bimanual exam, as she was uncomfortable and I did not feel that was a critical part of her exam.

20. Mrs. Freitas asked me what caused her pain with the exam and if it was "her mesh" and I responded that it was not part of the IME for me to reveal to her my physical exam findings and share opinions.

21. After the exam, I asked Mrs. Freitas to dress and then exited the room. Once she was dressed, I reentered the room and then sat down next to her. I asked her if she would like to use the restroom. She said yes, so I showed her to the bathroom that was one room away. After she exited the bathroom, I informed her that the IME was complete and that she was free to leave. I walked out to the waiting area with her where her cab was waiting and she left.

22. At that point she was not crying, she had regained her composure, there were no signs of bleeding, and she did not appear in distress.

23. I had no other patients or exams that day and never rushed her.

24. I have been in practice for 14 years and have performed over 1,000 pelvic exams per year. I often examine patients with pelvic pain from a variety of conditions. I feel it is vital in making a diagnosis or formulating an opinion to perform an exam on the area of concern. I make every effort to perform the exam as thoroughly, carefully, and gently as possible. That is what I did during Mrs. Freitas's exam. Patients are always allowed to refuse or stop an exam in progress. I do explain to the patient that this leads to an incomplete exam and less reliable opinions.

25. In rare circumstances (1/1000) we will need to perform an exam under anesthesia. This may include children, patients with mental or physical disabilities, fistula, and prior

radiation. The fact that Mrs. Freitas's other providers and Dr. Margolis were able to perform a pelvic exam without anesthesia informed me that exam under anesthesia was not indicated.

26. I examined Mrs. Ruiz on February 29, 2016 at the Centennial Medical Center in Centennial, Colorado, located at 13111 East Briarwood Avenue, Suite 105. I learned at the examination that the wrong address had been mistakenly provided to Plaintiffs' counsel. The incorrect address that was provided was 1311 East Briarwood Avenue, Suite 105. I was not involved in confirming the correct address for the examination.

27. At the beginning of my IME of Mrs. Ruiz, I explained to her the expectations of the IME, that a Doctor-patient relationship would not be established, and that there would be no expectation that I would treat her in the future.

28. Mrs. Ruiz elected to travel to the IME alone. She decided to travel without any friends or family.

29. I informed her that the IME would be similar to a consultation she would have with an Urogynecologist, Gynecologist or Urologist. She informed me she ran her husband's GYN office for 17 years and understood what I did and what was about to occur.

30. The IME took one hour and a majority of the time—approximately 50 minutes—was spent taking her history.

31. Part of taking a history is reading back to the patient what you heard to have them confirm the accuracy. This gives the patient an opportunity to correct anything that was not conveyed correctly. The HPI (history of present illness) is a narrative composed by the physician that summarizes the patient's current complaints. The CC (Chief complaint) is verbatim of what the patient tells you. The IME report is not a transcript.

32. Part of the IME is a physical exam, and as I noted above, it is a basic medical principle to do a complete exam and especially focus the exam on the area of concern. This area was the pelvis, vagina, and the prior surgical site.

33. As with my IME of Mrs. Freitas, before the physical exam, I made arrangements for a medical assistant from the office at which I was performing the IME to be present as an assistant. The medical assistant was present the entire time I examined Mrs. Ruiz.

34. I explained to Mrs. Ruiz what I was about to do during each portion of the exam. I gave her the option of deferring on the exam, but did stress to her the importance. Mrs. Ruiz elected to proceed with the exam.

35. Following her permission I inserted the plastic speculum into her vagina. She tolerated the exam well; she never had any overt signs of pain, crying, grimace, bucking or withdrawing.

36. My physical exam findings are documented in my IME report.

37. I did ask her to estimate her pain when I palpated various areas in the vagina, what is commonly known as pain mapping. I asked her to rate her pain in each area on a score of 0-10. She asked for me to give her an example of what 2/10 pain would be and I reported a toothache, 10/10 pain would be the worst pain imaginable, 4/10 pain would pain that “would require a pain pill.”

38. After the exam, I asked Mrs. Ruiz to dress and then exited the room. Once she was dressed, I reentered the room and then sat down next to her. I asked her if she would like to use the restroom. She said yes, so I showed her to the bathroom that was one room away. After she exited the bathroom, I informed her that the IME was complete and that she was free to

leave. I walked out to the waiting area. I helped her call her driver. She asked that I wait with her until her driver arrived. At her request, I waited with her until her ride arrived and she left.

39. At that point she was not crying, she did not appear in distress.

40. I had no other patients or exams that evening and never rushed her.

41. I have been in practice for 14 years and have performed over 1,000 pelvic exams per year. I often examine patients with pelvic pain from a variety of conditions. I feel it is vital in making a diagnosis or formulating an opinion to perform an exam on the area of concern. I make every effort to perform the exam as thoroughly, carefully, and gently as possible. That is what I did during Mrs. Ruiz's exam. Patients are always allowed to refuse or stop an exam in progress.

42. I never scowled at Mrs. Ruiz.

43. I never trivialized Mrs. Ruiz's complaints.

44. I was never rough during my exam.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on Tuesday, March 8, 2016, at Golden, Colorado.

/s/Brian J. Flynn
Brian J. Flynn, M.D.